Translation

PCT/JP2003/011211

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | |
|---|---|---|
| Applicant's or agent's file reference<br>Y0351-PCT | **FOR FURTHER ACTION** | See Form PCT/IPEA/416 |
| International application No.<br>PCT/JP2003/011211 | International filing date (*day/month/year*)<br>02 September 2003 (02.09.2003) | Priority date (*day/month/year*)<br>03 September 2002 (03.09.2002) |
| International Patent Classification (IPC) or national classification and IPC<br>A61K 31/18, A61P 13/02, 29/00, 43/00 | | |
| Applicant<br>YAMANOUCHI PHARMACEUTICAL CO., LTD. | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☒ Box No. I Basis of the report
   ☐ Box No. II Priority
   ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   ☐ Box No. IV Lack of unity of invention
   ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   ☐ Box No. VI Certain documents cited
   ☐ Box No. VII Certain defects in the international application
   ☐ Box No. VIII Certain observations on the international application

| | |
|---|---|
| Date of submission of the demand<br>13 February 2004 (13.02.2004) | Date of completion of this report<br>07 June 2004 (07.06.2004) |
| Name and mailing address of the IPEA/JP<br><br>Facsimile No. | Authorized officer<br><br>Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/011211

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

rnational application No.
PCT/JP03/11211

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 6, 7

because:

☒ the said international application, or the said claims Nos. 6, 7 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matters of claims 6 and 7 relate to methods for treatment of the human body by therapy, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 6, 7.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

national application No.
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**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | | YES |
| | Claims | 1-5 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-5 | NO |
| Industrial applicability (IA) | Claims | 1-5 | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

Document 1: Spinal Substance P Immunoreactivity Is Enhanced by Acute Chemical Stimulation of the Rat Prostate, (M. Ishigooka), Urology, January 2002, Vol. 59, No. 1, pages 139-144
Document 2: Design of a Multicenter Randomized Clinical Trial for Chronic Prostatitis/Chronic Pelvic Pain Syndrome, (K. J. Propert), Urology, June 2002, Vol. 59, No. 6, pages 870-876
Document 3: Painful Ejaculation and Urinary Hesitancy in Association with Antidepressant Therapy: Relief with Tamsulosin, (K. Demyttenaere), European Neuropsychopharmacology, August 2002, Vol. 12, No. 4, pages 337-341
Document 4: A Dose-ranging Study of the Efficacy and Safety of Tamsulosin, the First prostate-selective $\alpha_{1A}$-adrenoceptor Antagonist, in Patients with Benign Prostatic Obstruction (Symptomatic Benign Prostatic Hyperplasia), (P. Abrams), British Journal of Urology, 1997, Vol. 80, No. 4, pages 587-596
Document 5: JP, 2001-288115, A (Yamanouchi Pharmaceutical Co., Ltd.), 16 October, 2001 (16.10.01)
Document 6: EP, 1203582, A1 (Yamanouchi Pharmaceutical Co., Ltd.), 8 May, 2002 (08.05.02)
Document 7: EP, 1088551, A1 (Yamanouchi Pharmaceutical Co., Ltd.), 4 April, 2001 (04.04.01)
Document 8: National Institutes of Health Chronic Prostatitis Symptom Index for Japanese Men, (Y. Kunishima), Urology, July 2002, Vol. 60, No. 1, pages 74-77

[1] The subject matters of claims 1-5 do not appear to be novel or to involve an inventive step in view of documents 1-7 cited in the ISR.

Documents 1-7 describe medicinal compositions with tamsulosin as an active ingredient used for treatment of dysuria, and documents 1-4 describe that it can be used for treatment of pain corresponding to chronic pain in the pelvic cavity.

Documents 5-7 do not contain concrete disclosures on the activities of the said compound against chronic pain in the pelvic cavity; however, it is well known that dysuria is a cause of chronic pain in the pelvic cavity (see documents 1-4, document 8 presented by the applicant, etc., if necessary), and the pharmaceutical compositions for treatment of chronic pain in the pelvic cavity to which claims 1-5 of the present application relate, are aimed at diseases caused by dysuria. Accordingly, they are indistinguishable in terms of the medicinal uses.